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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,948	10/28/2005	Peter Frank Ekhart	0470-050777	7559

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EXAMINER

BLAND, LAYLA D

ART UNIT	PAPER NUMBER
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1623

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04/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,948	Applicant(s) EKHART ET AL.	
	Examiner LAYLA BLAND	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 15-27, 29 and 32-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 15-27, 29 and 32-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 9, 2009 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed February 9, 2009, and amendment and response to the Final Office Action (mailed August 8, 2008), filed February 9, 2009 wherein claims 12, 15-19, 24-27, 29, 32-33, and 35 are amended, claim 28 is canceled, and claims 37-46 are newly submitted.

Claims 13, 15-27, 29, and 32-46 are pending and are examined on the merits herein.

Withdrawn Rejections/Objections

Applicant is notified that any outstanding rejection/objection that is not expressly maintained in this office action has been withdrawn or rendered moot in view of applicant's amendments and/or remarks.

Priority

Applicant argues that paragraph 24 of priority Application No. EP 02078684.4 states "The glucans may also contain 1,3 and 1,6 linkages." The examiner was unable to locate this particular statement in paragraph 24, which is reproduced below:

[0024] The glucans to be used according to the invention contain, as a result of their branched nature, at least two types of linking one AGU to another. The type may be 1,2-linking, 1,3-linking, 1,4-linking or 1,6-linking. The glucans of the invention contain at least 1,6-linkages. Preferably the branched α -glucans contain both 1,4-linkages and 1,6-linkages, the branching units being 1,4,6-linked and amounting to at least 8% of the AGU. The glucans may have an average molecular weight of at least 10^5 Da, preferably at least $5 \cdot 10^5$ Da, more preferably at least $2.5 \cdot 10^6$ Da, up to e.g. 10^9 , in particular up to 10^8 Da. The glucans are preferably non-ionic, and more preferably non-derivatised, although a degree of substitution with e.g. acyl groups, carboxyl groups, hydroxyalkyl groups up to about 5% will be acceptable.

However, it is considered that the recitation above, that the types of glucan may be 1,2-linking, 1,3-linking, 1,4-linking or 1,6-linking is sufficient to provide support for the limitations of claim 33. Thus, the filing date of claim 33 is deemed to be the filing date of priority Application No. EP 02078684.4, September 9, 2002.

Information Disclosure Statement

All references of the IDS submitted September 4, 2007 have been considered.

The following is a new rejection:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 44 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 44 is drawn to a method of claim 13, "wherein satiety and satiation are induced while lowering the caloric content." Claim 13 is drawn to the administration of reuteran and does not refer to caloric content. There is insufficient antecedent basis for this limitation in the claim, and the meaning of the limitation is unclear. It is unclear which item or composition's caloric content is to be lowered, how it is to be lowered, and by how much it is to be lowered. Similarly, claim 45 is drawn to the method of claim 13 and includes the limitation "while lowering the glycemic index." There is insufficient antecedent basis for this limitation in the claim, and the meaning of the limitation is unclear. It is unclear which item or composition's glycemic index is to be lowered, how it is to be lowered, and by how much it is to be lowered.

The following rejections are maintained:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13, 15-27, 29, 32, 34, 35, 41, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Geel-Schutten et al. (Applied and Environmental Microbiology, 1999, pp. 3008-3014, Vol. 65(7), PTO-1449 submitted September 4, 2007).

Van Geel-Schutten et al. teach that polysaccharides are used as viscosifying, stabilizing, emulsifying, gelling, or water-binding agents in food industries, and that exopolysaccharides (EPS) produced from lactic acid bacteria are particularly desirable polysaccharides because lactic acid bacteria are food-grade organisms with GRAS status [page 3008, first paragraph]. Lactic acid bacteria and EPS contribute to the taste, smell, texture, and preservation of fermented milk products [page 3008, second paragraph]. One such EPS is produced from sucrose by the action of *Lactobacillus reuteri* [page 3008, third paragraph] (a preferred embodiment referred to as reuteran on page 5 of the instant specification). The glucan consists of terminal, 4-substituted, 6-substituted, and 4,6-disubstituted alpha-glucose in a molar ratio of 1.1 : 2.7 : 1.5 : 1.0 , indicating the presence of a branched glucan [page 3010, third paragraph].

Van Geel-Schutten et al. do not explicitly teach a food composition comprising reuteran or the administration of such.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a food composition, especially a fermented milk composition, comprising reuteran and to administer that composition to a subject. Van Geel-Schutten teaches the desirability of EPS produced by lactic acid bacteria (of which reuteran is one) in fermented milk products. Van Geel-Schutten suggests a food

product; the administration of a food product to induce satiety flows logically. It is within the skill of the skilled artisan to optimize the amount of reuteran for the desired taste, smell and texture.

Van Geel-Schutten et al. do not address the viscosity of aqueous solutions of glycogen at pH 6.8 and pH 2. However, this is an intrinsic property of reuteran. Further, Van Geel-Schutten et al. suggest the use of polysaccharides as viscosifying agents.

Response to Arguments

Applicant argues that Van Geel-Schutten does not teach the recited degree of branching. Van Geel-Schutten teaches exopolysaccharides produced by *Lactobacillus reuteri* from sucrose. The instant specification, paragraph 0028, defines "reuteran" as branched alpha-glucans obtained by the action of glucosyltransferase on sucrose having a degree of branching or 15% or more, and cites the Van Geel-Schutten reference. Thus, the exopolysaccharides produced by *Lactobacillus reuteri* from sucrose, as taught by Van Geel-Schutten, are "reuteran," a preferred embodiment in the instant application. Furthermore, Van Geel-Schutten does provide teachings regarding branching [page 3010, Methylation analysis] and molecular weight [page 3010, EPS size and monosaccharide analysis]. That data shows that about 16% of the glucose units comprising reuteran are 4,6-disubstituted (and thus branched).

Applicant argues that Van Geel-Schutten does not teach inducing satiety and satiation without increasing caloric intake. It is noted that the features upon which applicant relies (i.e., increasing satiation without increasing caloric intake) are not

recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that Van Geel-Schutten is non-analogous prior art. This is not persuasive because Van Geel-Schutten is drawn to EPS as a food additive which contributes positively to taste and smell of food. As mentioned above, the administration of a food product to induce satiety flows logically.

For these reasons, the rejection is maintained.

Claim 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Geel-Schutten et al. as applied to claims 13, 21-23, 15-19, 27, 41, 29, 24-26, 32, 34, 20, and 35 above, and further in view of Pucci et al. (US 4,877,634, October 31, 1989, of record).

Van Geel-Schutten et al. teach as set forth above, but are silent regarding caloric content and glycemic index of products comprising reuteran.

Pucci et al. teach polysaccharides produced by the fermentation of sucrose, which are useful for improving the texture, stability, or thickness of foods [see abstracts]. The polysaccharides were used as thickeners for milk drinks [column 6, Example 7] or ice cream or frozen yogurt [columns 7 and 8, Example 9]. The ice cream preparation had fewer calories as a result of replacing some of the whipping cream and milk with the thickener. Claims 44 and 45 are vague and indefinite, as set forth above. However, if the claims are intended to draw to manipulation of calories and glycemic index of foods

by addition of reuteran, it would be obvious for the skilled artisan to do that. Pucci teaches that replacement of whipping cream and milk with polysaccharides produced from fermentation of sucrose results in ice cream with fewer calories. The skilled artisan would also understand that removal of carbohydrate calories would very likely lower the glycemic index of a given food. Because reuteran was taught to be useful as a food additive for similar uses as Pucci's polysaccharide and because Pucci's polysaccharide is also prepared from fermentation of sucrose, as is reuteran, the skilled artisan could reasonably expect similar effects using either.

Claims 15, 16, 18-20, 24, 29, 32-34, 36-40, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cote et al. (US 5,786,196, July 28, 1998, of record) in view of Ritchey et al. (US 5,688,547, November 18, 1997, of record).

Cote et al. teach that high-molecular weight alternan consists primarily of α -1,3-linked and α -1,6-linked glucose residues with approximately 10% branching [column 1, lines 10-17]. Alternan is synthesized from sucrose via the enzyme alternan-sucrase [column 1, lines 23-24]. Alternan has potential as a substitute for gum arabic and for use as a bulking agent in foods, particularly as noncaloric, carbohydrate-based soluble food additives in artificially sweetened foods [column 1, lines 34-39].

Cote et al. do not exemplify a food composition comprising alternan.

Ritchey et al. teach an artificially sweetened meal replacement composition [see abstract], which comprises dietary fiber such as guar gum in an amount of 1-66% by

weight, and 4-86% by weight of protein [column 4, lines 24-64]. In one example, gum arabic was used at 6.25% and whey protein concentrate at about 12% [column 5, Example 1]. The composition can be used as a shake or a mousse to induce satiety [see abstract].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a food composition comprising alternan and at least 1 wt% of a food protein and to administer the composition. Cote et al. suggest the use of alternan as an alternative to gum arabic and an additive to artificially sweetened foods. Ritchey et al. teach one example of an artificially sweetened food which comprises gum arabic. Thus, the skilled artisan could conceive of replacing the gum arabic in Ritchey's composition with alternan and administering the composition.

Response to Arguments

Applicant argues that Cote is directed to low-molecular weight fractions. Indeed, portions of the Cole reference refer to low-molecular weight fractions. However, the portion of the reference which was relied upon, column 1, lines 24-39, state that "high-molecular weight alternan may be produced," and "this compound," as well as low-molecular weight products produced therefrom, "lend themselves to potential commercial applications as substitutes for gum arabic, for use as bulking agents and extenders in foods and cosmetics, particularly as noncaloric, carbohydrate-based soluble food additives in artificially sweetened foods." Thus, Cole teaches the benefits of both the high-molecular weight alternan and the low-molecular weight alternan.

Applicant argues that Cote does not teach that alternan can be used to induce satiety and satiation without increasing caloric intake. It is noted that the features upon which applicant relies (i.e., increasing satiation without increasing caloric intake) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Supervisory Patent Examiner, Art Unit 1623

/Layla Bland/
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